

June 19, 2012

The Honorable Tom Harkin, Chairman  
Senate HELP Committee  
Washington, D.C. 20510

The Honorable Mike Enzi, Ranking Member  
Senate HELP Committee  
Washington, D.C. 20510

The Honorable Fred Upton, Chairman  
House Energy and Commerce Committee  
Washington, D.C. 20515

The Honorable Henry Waxman, Ranking Member  
House Energy and Commerce Committee  
Washington, D.C. 20515

**Subject: Support for S. 3187, the Final Version of "FDA Safety and Innovation Act"**

Dear Chairman Harkin and Senator Enzi:

The National Community Pharmacists Association (NCPA) is writing to express our support for the final version of the revised FDA Safety and Innovation Act, released Monday, June 18, 2012. We commend you and your staff for all of the hard work that has gone into the process of developing this legislative package, and the transparency with which the process has been conducted. NCPA represents the owners and operators of 23,000 independent community pharmacies in the United States. Our pharmacies provide about 41 percent of all outpatient prescription dispensed in the United States, and will be affected by many provisions in this bill.

**Addresses DEA Issues Regarding Drug Shortages:** NCPA commends the Congress for tackling the difficult issue of prescription drug shortages. While most of the reported shortages to date have come from institutional settings in the sterile injectable area, community pharmacies have also experienced shortages of certain medications, primarily in drugs which treat ADD and ADHD. We believe that these controlled substances are in short supply, in part, due to the inflexibility of the current DEA quota system, which limits the quantity of certain medications that manufacturers can produce in any given year. Therefore, we were pleased to note the inclusion of language that will require the DEA to provide timely approvals or denials of manufacturer requests for increases of quotas of Schedule II controlled substances in circumstances in which an increase could help address a drug shortage situation.

**Downstream Supply Chain Security:** Although language on this topic was not ultimately included in the final bill due to time constraints, NCPA commends the Congress for facilitating consensus building discussions on this important and timely topic. We appreciate these efforts and the inclusive nature of these discussions that allowed for input from critical stakeholders. We especially commend Senators Bennet and Burr for all their hard work and commitment in this regard, and their concerns about the impact of new proposals on small businesses. We look forward to continuing discussions on how to further strengthen our already safe pharmaceutical supply chain.

**Creates Multi-Pronged Approach to Combat Drug Abuse:** NCPA is very supportive of multiple provisions included in the final bill that are designed to address the increasing problem of drug abuse.

- **GAO Study on Illegal On-line Pharmacy Websites:** NCPA is supportive of this initial “fact-finding” approach to this problem. A thorough study of the problem and the affected parties will ensure that this problem is corrected without disrupting the activities of traditional community pharmacies that maintain a website to assist their patients in ordering refills.
- **Interoperability of Prescription Drug Monitoring Programs:** NCPA is supportive of the provision that would allow the Secretary of HHS to facilitate the exchange of prescription drug information (PDMP programs) across state lines to prevent abuse. These efforts will provide pharmacists with critical information necessary to stem increasing tide of prescription drug abuse.
- **Report on Current Federal Initiatives to Ensuring Safe Use of Prescription Drugs:** NCPA is supportive of this provision that would also require HHS to identify both gaps and opportunities for further advancement on this issue.

We appreciate the opportunity to provide our support for this critical package of legislation and look forward to working with you in the future. Thank you also to the Committee staff.

Sincerely,



John M. Coster, Ph.D., R.Ph.  
Senior Vice President, Government Affairs

cc: The Honorable Harry Reid, Senate Majority Leader  
The Honorable Mitch McConnell, Senate Minority Leader  
The Honorable John Boehner, Speaker of the House  
The Honorable Eric Cantor, House Majority Leader  
The Honorable Nancy Pelosi, House Minority Leader